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Process optimization of tablet compression and coating of some model formulations using quality by design approach

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Meeting regulatory requirement demands in today's world is not an easy cakewalk and warrants a clear concept of all parameters being associated. The current research work proposes a censored experimental design and optimization model in the context of robust design to define the baseline parameters that yield compatibility and reproducibility throughout all circumstances. The concept of QbD could be successfully implemented in compression and coating stages. For similar geometry of tablet presses, similar process parameters could be reproduced in all machines with minimal impact on tablet properties in terms of hardness, thickness, disintegration time and variability. Similarly, minor change in main compression force will have significant impacts on tablet properties. Other variables like Turret Speed, Pre-compression force and feeder speed does not have a significant impact on tablet properties. The critical parameters for optimization for model formulation compression stage found to be a main compression force. QbD approach can be successfully implemented to optimize the coating process of film-coated tablets, the optimum inlet temperature, atomization air pressure and spray rate. A slight variation in spray rate has a major impact on the % LOD as well as Ra value. Spray rate was found to be major critical process variables because with the increase in spray rate Ra value decreases and % LOD value increases. Environmental Equivalency (EE) Factor was successfully implemented to optimize parameters and ideal coating activity. The combination of statistical design and technical design using QbD approach can yield robust tablets.

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